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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,478	06/10/1998	PLOWMAN GREGORY D.	235/054	9689

22249 7590 04/09/2002

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	16

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/095,478	Plowman et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-5, 7, 9, and 23-34* is/are pending in the application.

4a) Of the above, claim(s) *7* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-5, 9, and 23-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of Referances Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Peper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Acknowledgment is made of applicant's election, without traverse, of Group I, drawn to polynucleotides, in Paper No. 7 and the election, without traverse, of PTP10 polynucleotides in Paper No. 14.

2. Claims 1, 6, 8 and 10-22 have been canceled. Claims 2, 3, 5 and 9 have been amended. Claims 23-34 have been added. Claims 2-5, 7, 9 and 23-34 are pending. Claim 7, dependent upon canceled claim 6, is withdrawn from consideration. Claims 2-5, 9 and 23-34 are examined on the merits.

Specification

3. The disclosure is objected to because of the following informalities:

(A) Page 1, lines 9-10 refers to the title of the priority document as "Diagnosis and Treatment of ALP Related Disorders". However, the correct title of the provisional application is "Diagnosis and Treatment of PTP Related Disorders".

(B) Page 99, lines 6-7 and line 10 contains references to Lyon and Lyon docket numbers.

(C) Page 31, line 3 has modulator misspelled as "modular".

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 2-5, 9, 24, 26, 27, 29-34 and claims 25 and 28, in part, are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility.

The instant invention is drawn to the polynucleotides encoding the PTP10 polypeptide. The specification gives confliting teachings regarding the nature of the PTP polypeptide. The

specification teaches that the polypeptide of the invention comprises a "full length" amino acid sequence set forth in SEQ ID NO:8 (page 23, lines 5-8) which has 122 amino acid residues (Sequence Listing) and is encoded by the polynucleotide sequence of SEQ ID NO:4 (321 nucleotides according to the Sequence Listing). On page 91 of the specification it is stated that partial sequences of rat PTP10 are shown in SEQ ID NO:4 (nucleic acid) and SEQ ID NO:8 (amino acid). Page 93 of the specification states that two different rat PTP10 transcripts were identified by Northern analysis and found to be 3.3 and 1.8 KB, both numbers being far in excess of the 0.3 KB of SEQ ID NO:4. Thus it must be concluded, in agreement with the teachings on page 91 of the specification but in opposition to the teaching on page 23, that SEQ ID NO:4 is a partial nucleotide sequence and the polypeptide encoded by the expression of SEQ ID NO:4 is a partial amino acid sequence. The specification alleges that this partial amino acid sequence is a protein tyrosine phosphatase due to homology to PTP05 (page 32, lines 23-24). The specification teaches that PTP10 is homologous to part of the catalytic region of PTP05 (page 91, lines 7-13 and Figure 1B). However, the specification does not provide objective evidence that the PTP10 polypeptide, having only a portion of the phosphatase catalytic site, would retain tyrosine phosphatase activity as the catalytic site is not a complete catalytic site.

The specification gives conflicting teachings regrding the expression of the claimed polynucleitdes. SEQ ID NO:4 encoding SEQ ID NO:8 was isolated from rat basal forebrain (page 87, lines 4-5). Both PCR and Northern analysis corroborated the expression of PTP10 exclusively in rat testis (page 93, lines 13-15 and page 93, line 26 to page 94 line 4). However, on page 4, lines 2-4 it is stated that the tyrosine phosphatase disclosed by the instant invention are expressed in hematopoietic cells. With the exception of a low level of expression of PTP05 in cells or tissues of hematopoietic or immune origin, no expression of PTP10 was detected in hematopoietic cells or tissues. It must be concluded that PTP10 is not expressed in hematopoietic cells. Further, the instant application does not disclose the biological role of this polypeptide or its significance and one of skill in the art cannot rely on PTP10 pocessing protein tyrosine phosphatase activity as it represents a fragment of the protein tyrosine phosphatase catalytic domain, for the reasons set forth above.

The specification asserts on page 3, lines 17-26:

> It is well established that the abnormal or inappropriate activity of tyrosine kinases and or tyrosine phosphatase plays a role in a variety of human disorders including cell proliferation disorders such as cancer, fibrotic disorders, disorders of the immune system and metabolic disorders such as diabetes. A need, therefore, exists to identify new tyrosine kinases and phosphatase as a first step in understanding a disease process and the subsequent identification of therapeutic treatments for the disorder.

The specification asserts that it provides a method for treating or preventing an abnormal condition, such as cancer, by the modulation of PTP10 function, wherein said condition is characterized by abnormality in PTP10 signal transduction (page 31, lines 1-6).

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the polynucleotide fragment encoding SEQ ID NO:8 of the instant invention. The disclosed polypeptide PTP10 is said to have a potential function based upon its amino acid sequence similarity to PTP05 and other protein tyrosine phosphatase (page 91, lines 7-13). After further research, a specific and substantial credible utility might be found for the claimed PTP10 polynucleotide or the polypeptide encoded thereby. This further characterization, however, is part of the act of invention and until it has been undertaken the claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to

> be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a polynucleotide fragment of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the PTP10 (SEQ ID NO:8) or the polynucleotides encoding PTP10 of the instant application was, as of the filing date, useful for the prevention or treatment of cancer as stated at page 3 of the specification. Until some actual and specific significance can be attributed to the polypeptide identified in the specification as PTP10, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

The DNA of the instant invention and the protein encoded thereby are compounds which share some structural similarity to the catalytic region of protein tyrosine phosphatases. Protein tyrosine phosphatases share several common structural motifs, including the catalytic site. Some of these proteins have different sites of action and different biological effects. For instance, the mRNA encoding the receptor-like protein tyrosine phosphatase alpha is found to be upregulated in late stage colon cancer (Cancer Letters, 1995, Vol. 93, pp. 239-248), protein tyrosine phosphatase activity has been shown to decrease in colorectal cancer (Anticancer Research, 1996, Vol. 16, pp. 943-946), protein tyrosine phosphatase IA-2 is differentially expressed in neuroendocrine-type human lung cancer cells (Cancer Research, 1996, Vol. 56, pp. 2742-2744), protein tyrosine phosphatase LAR suppresses insulin receptor activation (Cell signaling, 1996, Vol. 8, pp. 467-473), protein tyrosine phosphatase beta2 induces terminal erythroid cell differentiation (J Biological chemistry, 1996, Vol. 29, pp. 30916-30912), cdc25 is a tyrosine phosphatase that activates p34 and is required for progression through the cell cycle (J biological chemistry, 1999, Vol. 274, pp. 7958-7968). Given the above teaching of the diverse activity attributed to the family of protein tyrosine phophatases, it is not clear if the polypeptide of the instant application would be directly or inversely associated with tumorigenesis, suppress or

activate a receptor or protein, inhibit or activate cell proliferation or differentiation. In the absence of knowledge of the protein or receptor which is activated or deactivated by interaction with PTP10, or a significant biological attribute associated with PTP10, such as a direct or inverse association with a specific tumor type, there is no immediately evident patentable use for it. To employ the polynucleotides encoding PTP10 or the polypeptide encoded thereby of the instant invention in the treatment or prevention an abnormal condition, such as cancer (page 31, lines 1-6) would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for PTP10, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

The instant specification asserts that nucleic acid probes derived from the polynucleotides which encode PTP10 can be useful to obtain another nucleic acid molecule of the instant invention (page 25 and page 36). The instant specification further asserts that PTP10 can be used for the production of an antibody having specific binding affinity to PTP10 for use in diagnostic kits (page 24) detection of PTP10 (page 36) and in the screening of cells for identifying natural binding partners of PTP10 polypeptides and in a method of identifying a substance capable of modulating the function of the PTP10 polypeptide (page 26).

These asserted utilities for PTP and the polynucleotides encoding PTP10, such as production of and screening of antibodies, antagonists and agonists and the generation of nucleic acid probes to identify other related polynucleotides, apply to many unrelated polypeptide and all polynucleotide sequences. Therefore these asserted utilities are not considered specific utilities, as they are not specific to PTP10.

Furthermore, in order for a polynucleotide to be useful, as asserted, for treatment of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a specific disease or disorder. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used either in a diagnostic manner or in a therapeutic manner. Many proteins are expressed in normal

tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any specific disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2-5, 9, 24, 26, 27, 29-34 and claims 25, 26 and 28, in part, are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2-5, 9 and 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 9, 23, 24 and 27 are drawn to the non-elected polynucleotides of PTP05. For purpose of examination, the claims will be read as drawn only to PTP10 polynucleotides.

Claim 23(a) recites "...a nucleotide sequence that encodes a polypeptide having an amino acid sequence that differs from the sequence set forth in SEQ ID NO:8", but fails to recite the difference between the claimed sequence and SEQ IS NO:8.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 23 and claims 25 and 28, in part, are rejected under 35 U.S.C. 102(b) as being anticipated by Maekawa et al (FEBS Lett, 1994, Vol. 337, pp. 200-206).

Claim 23 (a and b) is drawn to a nucleic acid comprising a nucleotide sequence that encodes a polypeptide having an amino acid sequence that differs from the sequence set forth in SEQ ID NO:8, and the complement thereof. Claims 25 is drawn in part to the nucleic acids of claim 23, further comprising a heterologous nucleic acid sequence. Claim 28 is drawn in part to the nucleic acids of claim 23, further comprising nucleic acid sequences encoding restriction endonuclease sites.

Maekawa et al disclose a nucleic acid comprising a cDNA encoding a protein-tyrosine phosphatase which differs from the sequence of SEQ ID NO:8. Maekawa et al disclose a vector comprising said cDNA, said vector having nucleic acid comprising restriction endonuclease sites located 5' and 3' to the inserted cDNA for ease of manipulation of the nucleic acid sequence.

12. In the event that applicant is able to overcome the rejection under 35 U.S.C. 101, above, the following rejections would apply:

13. Claim 2-5, 9, 24, 26, 27, 29-34 and claims 25, 26 and 28, in part, would be rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims would be enabling only for nucleic acid molecules consisting of SEQ ID NO:4, nucleic acid molecules consisting of a polynucleotide encoding SEQ ID NO:8, or nucleic acid molecules obtained from a rat which hybridize under stringent conditions to the complement of polynucleotides consisting of nucleic acids encoding SEQ ID NO:8 as the specification does not provide adequate written description for nucleic acid molecules comprising SEQ ID NO:4 or nucleic acid molecules comprising a polynucleotide encoding SEQ ID NO:8, or nucleic acids which hybridize under highly stringent conditions to a nucleic acids comprising a polynucleotide sequence which encodes SEQ ID NO:8, or nucleic acid molecules, wherein said nucleic acid molecule is isolated from a mammal other than a rat.

The written description in this case only sets forth SEQ ID No: 4 and the polynucleotides encoding SEQ ID NO:8. For the reasons set forth above, it is clear that SEQ ID NO:4 and the polynucleotide encoding SEQ ID NO:8 represent a fragment of a protein coding region. When given the broadest reasonable interpretation, the claims encompass a variety of species including full-length cDNAs, genes, full length protein coding regions, and artificial chromosomes. Therefore the written description is not commensurate in scope with the claims drawn to nucleic acids comprising SEQ ID NO:4 or nucleic acids comprising polynucleotides encoding SEQ ID NO:8.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. (See page 1117). The specification does not clearly allow persons of

ordinary skill in the art to recognize that applicant invented what is claimed. (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Claim 3 specifically drawn to nucleic acid molecules which are isolated from the genus of a mammal and hybridizes to nucleic acids comprising the disclosed polynucleotides. Claim 4 further specifies that the claimed nucleic acids are isolated from a human. The specification does not teach more than SEQ ID NO:4, isolated from the rat.

In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that an adequate written description of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Thus claims to a broader genus of nucleic acids based only on the ability of said nucleic acid to hybridize to the disclosed nucleic acids do not satisfy the written description requirements absent specific teaching regarding the detailed structure of the nucleic acids claimed, i.e., the actual nucleic acid sequences.

Furthermore, the gene encoding the full length cDNA transcript comprising SEQ ID NO:4 would be expected to have both introns and exons as well as regulatory elements. The specification teaches that in murine testis mRNA transcripts of approximately 3.3 KB and 1.8 KB hybridized to the polynucleotides encoding PTP10. The specification does not teach the cDNA encoding these said transcripts of a gene which expresses said transcripts. Thus, the structure of a gene or cDNA comprising SEQ ID NO:4 or the polynucleotides encoding SEQ ID NO:8 is not defined

With the exception of the polynucleotides consisting of SEQ ID NO:4 or a nucleic acid consisting of polynucleotides encoding SEQ ID NO:8, the skilled artisan cannot anticipate the sequences of the genes and cDNA encompassed by the claims and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Given the lack of teaching in the specification regarding the specific nucleic acids beyond nucleic acids consisting SEQ ID NO:4 or nucleic acids consisting of polynucleotides encoding SEQ ID NO:8, there is insufficient data to support the generic claims as provided by the Interim Written Description Guidelines published in the January 30, 2001 Federal Register at Volume 66, Number 4, pages 1099-1111.

Therefore only an isolated nucleic acid comprising SEQ ID NO:4, and isolated nucleic acids consisting of a polynucleotides encoding SEQ ID NO:8 but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph.

14. Claim 24 and claims 25, 26 and 28, in part, would be rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 24 is drawn to a nucleic acid molecule comprising a nucleotide sequence that encodes a polypeptide having an amino acid sequence that differs from the amino acid sequence of SEQ ID NO:8 by lacking at least one, but not more than two, of the domains selected from the group consisting of an N-terminal domain, a catalytic domain and a C-terminal domain, or the complement of said nucleotide sequence. The specification teaches that PTP05 has an N-terminus which extends from residues 1-187, a catalytic domain extending from residue 188-420, a C-terminus extending from residues 421-426 (page 90, line 24 to page 91, line

10). The specification teaches that PTP10 has homology to part of the catalytic domain, residues 251 to 357 of PTP05 (figure 1B). Thus it can be concluded that PTP10 consists of a portion of the catalytic domain of PTP05. As the specification provides no teaching to contradict that PTP10 consist only of a partial catalytic domain, one of skill in the art could not make the nucleic acid of claim 24 as it is not possible to delete an N- or C- terminus which does not exist.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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April 4, 2002